

**REMARKS:**

Claims 15-23 were rejected under 35 USC 112. It is respectfully requested that the examiner reconsider this rejection. Specifically, it is noted that "visible/near-IR" is referred to throughout the application as filed, for example, at least at page 2, lines 23-31 and page 5, lines 26-32, and in that context, it would be understood by one of skill in the art that the beam used in the analysis is composed of visible and/or near-IR. This is further supported by the fact that the respective wavelength ranges listed on page 6, lines 4-9 state that wavelengths from both the visible and near-IR may be selected as may combinations of these wavelengths. Furthermore, it is noted that at least page 2, lines 13-20 describe how "visible and near-IR light is brought from a spectrophotometer to the skin via a fiber optic cable".

Claims 1, 3-6, 9-10, 12-19 and 21-23 were rejected under 35 USC 103(a) in view of Kenet.

Regarding Kenet, it is noted that the abstract of this reference deals primarily with multispectral digital images of body surfaces which are compared to subsequent similar body images. A database is also described which contains a series of images from a lesion together with the medical history of that lesion. This database can then be used for characterizing subsequent lesions. Finally, the abstract also mentions "classifying the features of [a] lesion according to the diagnostically useful classification of pigmented skin lesions". Thus, Kenet deals primarily with temporal-spatial distribution of light-absorbing characteristics of skin lesions, in particular, the depth of their subsurface extents. In other words, changes in the multispectral (red, green blue and infra-red) characteristics of lesions are monitored over time. These images can be used to reconstruct a 3-D surface map of the lesion. This may then be used to estimate pigment depth and/or density, or to estimate features of other subsurface structures or processes (US Patent 5,836,872, column 16, lines 1-3). Thus, the majority of the document deals with methods of recording digital images of lesions such that the lesions are mapped to their particular body portion so that any changes to size, color or morphology of the lesion over time can be easily detected on comparison with the recorded images. Furthermore,

multispectral images are taken so that changes to the distribution of pigment and other characteristics can also be monitored over time. This is not applicant's invention, which involves taking a spectrum of visible and/or near-IR light of a skin portion afflicted with a skin disease selected from the group consisting of: dysplastic melanocytic nevi; banal nevi; lentigines; actinic keratoses; seborrheic keratoses; basal cell carcinoma; and malignant melanoma; comparing that spectrum to a control skin portion and based on that comparison, determining what steps are needed next, for example, whether a biopsy is necessary or not. In the instant claims, an initial diagnosis of the skin lesion is done immediately, not based on changes over time. Furthermore, the differences between lesions that allow diagnosis with the present invention are based upon biochemistry, and are not morphological in nature. Thus it is not required to postulate a link between morphology and histology. In addition, the present invention is able to classify non-pigmented lesions, in addition to pigmented lesions.

As discussed above, Kenet does mention a classification system which is discussed in column 25, lines 21 to 48 of US Patent 5,836,872. However, this classification system is largely prophetic and basically states that a classification method could be created, for example, based on "a priori information about how morphologic and spectral features of pigmented cutaneous lesions correlate with microscopic pathological features thereof, a classification method may be employed by the invention that incorporates this a priori information into a classification scheme that would estimate the probability that a given cutaneous lesion belonged to a particular pathological class or diagnosis. Or for example, consider multispectral data and a priori information about the known spectral properties of certain pigments and other structures in the skin, then, a classification scheme could be employed by the invention that would classify each pixel as belonging to one, or possibly more than one, class..." Thus, while a classification scheme is envisioned, no formal classification scheme is taught. Furthermore, the envisioned scheme requires digital images for pixel analysis and/or morphological analysis of the lesion which is again not applicant's invention. Thus, Kenet suggests that it might be possible to create a

classification scheme but does not demonstrate that such a scheme would work. Furthermore, the schemes suggested by Kenet require additional analysis, either digital or morphological, not found in the instant claims. Finally, US Patent 5,836,872 assumes a priori knowledge of the relationship between pigmentation and lesion histology, an assumption not required in the present invention.

Claims 7 and 20 were rejected under 35 USC 103(a) in view of Kenet and in view of Jackson et al., Richards-Kortum et al or Soller et al. It is believed that the above arguments overcome this objection as well.

Claim 8 was rejected under 35 USC 103(a) as unpatentable over Kenet et al further in view of Haaland. It is believed that the above arguments overcome this objection as well.

Further and more favorable consideration is respectfully requested.

Respectfully submitted

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November 3, 2005

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